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ENVIRONMENTAL PROTECTION AGENCY

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TOXIC SUBSTANCES CONTROL

Proposed Implementation Approach; Request for Public Comment

[65-60-01-M]

ENVIRONMENTAL PROTECTION AGENCY

[OTS-260001; FRL 990-7]

TOXIC SUBSTANCES CONTROL

Proposed Approach To Implementing the Toxic Substances Control Act; Request for Public Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice, request for public comments.

SUMMARY: This document outlines EPA's current approach to implementing the Toxic Substances Control Act (TSCA). The present approach has evolved over the past several months and will continually become more sophisticated as EPA gains experience and develops a comprehensive strategy for implementing TSCA. The purpose of this document is to share EPA's current approach and invite public comments.

DATES: Comments should be provided by December 20, 1978.

ADDRESS: Comments should be addressed to Attention: Joyce Barbour, Office of Toxic Substances, (TS-793), Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460. Please mark comments with the identifying notation OTS-260001. All written comments will be available for public inspection in room 711, East Tower, from 9 a.m. to 4 p.m. Monday through Friday.

FOR FURTHER INFORMATION CONTACT:

Mr. John B. Ritch, Director, Office of Industry Assistance, Office of Toxic Substances (TS-799), Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460, 202-554-1404 or 800-424-9065 (toll free).

Dated: October 16, 1978.

STEVEN D. JELLINEK,
Assistant Administrator for Toxic Substances.

PROPOSED APPROACH TO IMPLEMENTING THE TOXIC SUBSTANCES CONTROL ACT

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PROPOSED APPROACH TO IMPLEMENTING THE TOXIC SUBSTANCES CONTROL ACT

PURPOSE

This document outlines EPA's current approach to implementing the Toxic Substances Control Act (TSCA). It sets forth the basic objectives for the early years of implementation, discusses major policy decisions already made by EPA, and identifies questions yet to be resolved.

The approach outlined here has evolved through several earlier drafts and will be succeeded by progressively more sophisticated versions as EPA gains experience and develops a comprehensive strategy for implementing TSCA. Furthermore, many issues are addressed only briefly in this presentation. Selected topics, such as unreasonable risk determinations under TSCA, will be covered in supplementary documents.

This document is primarily directed toward the people responsible for implementing TSCA and other Federal, State, and local programs concerned with controlling toxic substances. It is also intended for those with an informed interest in the matter, such as Members of Congress and their staff, and representatives of industry, labor, and public interest groups. It assumes general familiarity with TACA and with EPA activities so far, and focuses on important issues involved in implementing the Act.

INITIAL IMPLEMENTATION

Under the Toxic Substances Control Act, EPA is responsible for identifying chemical substances that present unreasonable risks to human health or the environment and for taking action to minimize the risks. To achieve TSCA's goals, EPA will concentrate in the early years of implementation on these objectives:

- Develop the necessary organization and staff.
- Define methods for assigning priority to chemical substances for investigation and regulation.
- Establish procedures for testing and evaluating chemical hazards.
- Initiate information gathering.
- Establish mechanisms for premanufacture notification of new chemical substances.
- Take selective regulatory actions.
- Develop a coherent agencywide approach to toxic substances.
- Work toward consistent international approaches to toxic substances control.

ORGANIZATION AND STAFF

The organization and staff to implement TSCA are almost entirely new. Unlike most other laws for which EPA is responsible, the predecessor program was extremely modest. When TSCA was enacted in October 1976, the toxic substances program had fewer than 50 people. To carry out the new responsibilities, a staff of 500 or more will be built up in the next few years. Recruiting and hiring a high-caliber staff with the necessary expertise is receiving high priority, and will require continuing time and effort.

DETERMINING PRIORITIES

The reach of the Toxic Substances Control Act is extremely broad. It encompasses some 70,000 chemical substances in commerce, not including thousands of others used for research and development. With the mandate to investigate risks from such a multitude of substances and to regulate where appropriate, EPA's actions must be selective. A major objective is to develop a system for assigning priority to chemical substances for investigation and regulatory action. Certain general principles will guide the process.

In all decisions under TSCA, the relative risk presented by a chemical substance will weigh heavily. Two principal factors define risk: Potential adverse effects and exposure. evaluation of a risk involves both policy and scientific considerations. For instance, assigning more or less importance to acute versus chronic effects raises basic policy questions. Potency—the magnitude of the probable effects that a substance will produce at various levels— and exposure both involve scientific determinations.

Taken together, the principal factors, potential effects and exposure, indicate the nature and degree of risk. To determine whether risks are "unreasonable" for purposes of actions under TSCA, EPA must consider another complex set of factors. Priority for taking action to reduce a risk may depend not only on the degree of risk but also on the magnitude of the social and economic costs and benefits of the action, and the effects of alternative substances which might be substituted for the substance in question. In general, good information on all the relevant factors will characterize substances which receive high priority for action. Yet, for some substances, the known severity of effects or the extent of estimated exposure may warrant a high priority for action despite uncertainties about other factors.

Priorities will also be affected by efficiency and resource considerations. A significant factor in EPA's decision to take action under TSCA will be the relative effectiveness of controlling the risk under TSCA, compared with some other legal authority. At the same time, EPA will explore alternatives to regulatory actions—measures, for example, which prompt industry to test substances or adopt appropriate

safeguards without mandatory requirements.

Priorities may be different for different activities. For example, limited knowledge about the effects of a chemical in high volume production might give the chemical a high priority for testing, but a low priority for control action. However, data developed under a testing requirement might lead to a decision to initiate control action. In some instances, if currently available data are inconclusive, limited regulatory action (such as labeling) might be taken, to warn of suspected hazards pending the collection of more definitive data.

EPA has already considered some kinds of effects to emphasize in setting priorities and has reached some working decisions. Some of the decisions are straight forward. For example, where acceptable tests for a particular effect are not available, EPA will not require testing. Other decisions are more complex.

In general, chemical substances suspected of producing chronic health effects will take higher priority than those with potential acute effects. The acute effects of chemical substances in commerce are better known and more easily controlled than are chronic or latent effects, which may appear after a long latency period or exposure over an extended period of time, and are thus much more difficult to identify.

Higher priority will be given to possible toxic effects that are irreversible or are slowly reversible and debilitating; included in these two categories are oncogenic, mutagenic, teratogenic, and neurotoxic effects. Consideration will also be given to cardiovascular, respiratory, immunological, dermatological, and reproductive effects. EPA will be more concerned with the severity and relative irreversibility of the effects than with which systems are affected.

In considering environmental effects, EPA will give high priority to substances which are both widely dispersed and also threaten human health (for example, through contamination of water supply), or else endanger commercially important species, or threaten to disrupt significant ecosystems. Toxic effects on individual plants or animals that do not threaten species populations or ecosystems will take lower priority. These criteria for determining priorities will be further developed and refined with experience.

HAZARD ASSESSMENT PROCESS

EPA has developed a multistage process for identifying substances of priority concern from among the tens of thousands of chemical substances under TSCA's purview. EPA will use these procedures to select the substances most likely to present unreasonable risks to human health or the environment. EPA will proceed step-by-step from initial selection of chemical substances for review, to a preliminary evaluation, to progressively more intensive assessments. Decisions will be made at the end of each stage whether to continue to the next. At the final stage there will be a detailed risk assessment adequate for initiating regulatory actions under TSCA or other relevant authorities.

Substances will first be selected on the basis of structure/activity correlations, biological activity, production volume, potential for environmental release and exposure, persistence, and other factors. On the basis of these criteria, EPA will score substances using a system based on that used by the Interagency Testing Committee.[1] In addition, candidates may come from several other sources, such as citizen's petitions, recommendations by other agencies, notices of substantial risk submitted under TSCA, monitoring data, or categories of particular concern (such as "flame retardants").

The initial evaluation will use readily available production, use, and effects data. It may prompt several possible actions: EPA may conduct a more thorough hazard assessment; develop additional information through reporting or testing requirements; refer the substance for further evaluation by other EPA programs or other Federal agencies; or designate the substance as "low priority." The results of the evaluation (reported in a Chemical Hazard Information Profile) and recommendations for action are then considered by an agencywide committee, the Toxic Substances Priorities Committee.[2]

Substances that EPA believes warrant further evaluation will undergo the next level of review. In addition to candidates selected from this process, EPA may select some from those reviewed by the Interagency Testing Committee or identified by review of substantial risk notices. During this phase, EPA will prepare a Chemical Source/Effects Report that summarizes the available effects data and analyzes possible sources of exposure associated with manufacturing, processing, distribution, use, and disposal. Preliminary control option papers will consider possible regulatory and nonregulatory measures. The Toxic Substances Priorities Committee will review these alternatives from the perspective of other EPA programs and authorities.

A decision to advance to the final assessment stage requires a commitment of substantial resources. In this final stage, EPA may conduct monitoring to develop or confirm estimates of exposure. The Office of Toxic Substances will prepare a Chemical Risk Evaluation Document that includes a detailed evaluation of effects and exposure data. Draft documents concerning the relative risks and benefits of the substance and possible actions will be circulated within EPA for review and comment. The Toxic Substances Priorities Committee will have an opportunity to discuss the options. After a decision that the risks should be addressed under TSCA or another of EPA's authorities, EPA's normal regulatory process will begin.

TESTING

One of the most important provisions of the Toxic Substances Control Act is the authority in section 4 to require manufacturers and processors to test chemical substances and mixtures for health and environmental effects. Very few substances have been tested for long-term or chronic effects. Additional testing of substances with potentially high exposure or those suspected of causing harmful effects will greatly help EPA to meet the objectives of TSCA.

As a first step, EPA is developing a series of test standards for different health and environmental effects. The standards will specify acceptable test protocols and methods for developing, analyzing and presenting test data. To the extent possible, these test standards will be consistent with those in the testing guidelines issued under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Because many substances have both pesticide and nonpesticide uses, discrepencies between the testing protocols required under TSCA and FIFRA could lead to costly duplication.[3]

The first standards will be to determine whether chemical substances are oncogens, or tumor-causing substances. The second standards will be for chronic effects on liver, kidney, reproductive, circulatory, and other organ systems. They will be followed by standards for acute and subchronic toxicity, chemical fate, and persistence. Further in the future, EPA will

[1] The Interagency Testing Committee, established by sec. 4(e) of TSCA, is responsible for recommending chemical substances for testing under sec. 4. In October 1977, the committee published their methods for selecting substances (42 FR 55026). The committee's work and relation to EPA are described in a following section.

[2] The composition and role of the Toxic Substances Priorities Committee are discussed in a later section.

[3] EPA is also working to insure that TSCA test standards are consistent with those of the Food and Drug Administration (FDA), Consumer Product Safety Commission (CPSC), Occupational Safety and Health Administration (OSHA), and other Federal agencies. This effort is primarily through the interagency regulatory liaison group (EPA, FDA, CPSC, and OSHA).

issue test standards for teratogenicity and reproductive effects, mutagenicity, and additional health and environmental effects.

Specific test standards under TSCA depend in part upon the availability of well-validated test methods. For example, there are no generally accepted test methods for some environmental effects. Nor are there short-term predictive tests for most health and environmental effects. An important part of EPA's program will be to develop and validate urgently needed testing methods. EPA will monitor advances in the state-of-the-art and revise prescribed testing standards accordingly.

Wherever possible, EPA plans to develop a hierarchical or sequential approach to testing requirements. Under this approach requirements for higher-level tests (such as long-term testing for oncogenicity) will depend in part on the results of lower-level tests (such as mutagenic tests). This approach will be most successful when reliable shortterm, inexpensive predictive tests are available. If such tests do not exist, such factors as the chemical structure of a substance, physical, and chemical properties, preexisting toxicity data, or extent of exposure, may be used to trigger testing.

Measures to insure that tests are properly conducted and accurately reported are critical to the success of the testing program. Recent disclosures of inaccurate or fraudulent test data submitted to the Government underline the importance of quality control.

EPA is developing standards for quality assurance that will prescribe general procedures for conducting tests required by TSCA. The standards will address a variety of factors that could affect the quality of the test data, including the training and experience of laboratory personnel, the care, feeding, and examination of test animals, the condition of laboratory equipment, and pathology procedures. To the extent possible, the standards for quality assurance will be consistent with the good laboratory practices developed by the Food and Drug Administration (FDA).

Enforcement of the testing and quality assurance standards through selected laboratory inspections and data audits will be an important aspect of the testing program. Under an interagency agreement, FDA will frequently conduct laboratory inspections for purposes of TSCA. If a laboratory is not in compliance, EPA will not accept the test results. Records kept during the course of an experiment will frequently be compared with the reported results. EPA may also examine pathology slides of test animal tissues to evaluate the reported conclusions.

The success of the testing program rests largely with the chemical firms and laboratories that will perform the testing. Industry's responsibility extends beyond minimal compliance with the testing requirements. EPA expects that if an unanticipated adverse effect is observed, the responsible party will make further tests or analyses. Similarly, if a firm considers a recommended test method inappropriate for a certain substance, it should propose an alternative.

The selection of chemical substances to be subjected to test standards is another critical aspect of the testing program. Under TSCA, if a substance may present an unreasonable risk or is produced in substantial quantities and may have significant human or environmental exposure, testing may be required as necessary to evaluate its risks. EPA's systematic hazard assessment process, described in the previous section, will identify candidate substances for testing. Each candidate will be screened further on the basis of previously developed data, structure/activity correlations, production volume, use and exposure information, and other factors.

In addition to the substances identified through the hazard assessment process, the Interagency Testing Committee (ITC) comprised of representatives of eight Federal agencies, may recommend substances or classes of substances for testing. For substances designated by the Committee for special attention, the Administrator must either begin rulemaking to require testing or publish his reasons for not doing so within 12 months after receiving the Committee's recommendation.

To date, the Interagency Testing Committee has recommended 21 chemical substances and classes of substances, in three groups. All have been designated for priority attention by EPA. In October 1977, the Committee provided its first set of recommendations which are: Alkyl epoxides; alkyl phthalates; mono- and di-chlorinated benzenes; chlorinated paraffins; chloromethane; cresols; hexachloro-1,3-butadiene; nitrobenzene; toluene; and xylenes. The second set submitted in April 1978 included: Acrylamide; aryl phosphates; chlorinated naphthalenes; dichloromethane; halogenated alkyl epoxides; polychlorinated terphenyls; pyridine; and 1,1,1-trichloroethane. The latest recommendations were received in October 1978: Tri-, tetra-, and penta-chlorinated benzenes; 1,2 dichloropropane; and glycidol and its derivatives.

As required by TSCA, EPA responded to the ITC's first set of recommendations within 12 months. Because EPA had not yet completed its review of the recommended substances and the development of suitable test standards, EPA published a FEDERAL REGISTER notice in October 1978 stating its reasons for not initiating rulemaking. Thus far, EPA has found that the October 1977 ITC recommendations seem appropriate. The initial testing rules for oncogenicity will probably encompass many of the ITC candidates.

RECORDKEEPING AND REPORTING REQUIREMENTS

A principal aim of the information program under TSCA is to meet the needs of potential data users without requiring duplication or otherwise imposing unreasonable burdens on industry. As a first step, EPA is identifying the specific information needs within EPA and other Federal agencies. At the same time, EPA is surveying existing information-gathering programs to determine the most efficient means of obtaining the desired information. To the extent possible, reporting requirements will be consolidated. In addition, EPA will survey the industry's current systems and policies for recordkeeping to assess the likely impacts of different approaches. On the basis of these and other studies, a plan for implementing TSCA's information-gathering authorities will be prepared.

In gathering information under section 8(a) EPA will use modular reporting rules, which recognize that different degrees of specificity are appropriate for different purposes. Reporting use information in general categories (e.g., "solvents used in consumer products") rather than in terms of specific applications (e.g., "solvents used in consumer products for spot removal") may be adequate for some purposes such as selecting substances for preliminary screening. Substances undergoing further assessment may require more detailed information. Eventually, several levels of reporting requirements may be developed for various kinds of information.

A primary goal for the next few years is to develop a data base that will help identify substances that may present the greatest risks. The collection of data under the inventory reporting requirements of December 1977 was a first step. Reports submitted under these requirements include chemical identity, production, and plantsite information for an estimated 70,000 substances in commerce. As a next step, EPA plans to require general use information for substances produced in substantial quantities or for substances identified as potential candidates for hazard assessment.

A uniform system for identifying uses is critical to accurate reporting and systematic data retrieval and analysis under TSCA. On July 25, 1978, EPA published approximately 850 terms describing chemical uses, and invited public comment on the applicability, utility, and technical merit of the proposed terms. This use classifi-

cation system could be used to gather data for hazard assessment, premanufacture notification, and other purposes. For screening substances for preliminary review, the 850 categories may be coalesced into a small number of broad categories. On the other hand, for purposes of regulatory actions EPA may define subcategories to obtain more explicit use information.

Definition of small manufacturers and processors. TSCA's section 8(a) provides that "small manufacturers and processors" are exempt from general reporting requirements except for information on chemical substances or mixtures subject to a proposed or final rule or order under TSCA. EPA is developing standards for determining which manufacturers and processors quality as "small."

Because the potential costs of different reporting requirements vary widely, EPA is seriously considering different standards for the "small manufacturer and processor" for different purposes. It is relatively inexpensive, for example, to supply data in broad production ranges or use categories for purposes of screening substances. On the other hand, it will be far more burdensome to report the extensive and precise information that may be necessary for specific regulatory purposes. EPA is currently analyzing available data and consulting with the Small Business Administration to determine whether different standards would be appropriate for successively more demanding requirements.

Selective approach to requirements. EPA intends to make selective use of reporting requirements. Before issuing a reporting requirement, EPA will determine what data are already available, and will direct most requirements to selected substances or categories. For example, EPA does not now intend to update the plantsite and production information collected for all substances under the initial reporting requirements. EPA needed this information to establish a profile of the chemical industry and to determine initial priorities based on production volumes and geographic considerations. As discussed above, EPA's next requirements under section 8(a) will concentrate on obtaining general use information for selected substances.

Compatible recordkeeping. EPA will encourage companies to design their recordkeeping systems to be compatible with the formats developed for TSCA, especially for health and safety data. Common formats will facilitiate analysis of information collected from a number of sources. In addition, EPA will prescribe a general format for keeping records of adverse effects under section 8(c).

Notices of substantial risk. Section 8(e) requires any person who manufactures, processes, or distributes a chemical substance in commerce to notify EPA immediately of "information which reasonably supports the conclusion" that such a substance "presents a substantial risk of injury to health or the environment." This provision was effective on January 1, 1977. In March 1978, EPA published a policy statement providing guidance for submission of 8(e) notices. The Agency had received approximately 240 notices by September 1978.

Each notice is reviewed as expeditiously as possible and any special problems are referred to the appropriate authority. The majority of notices so far have concerned workplace problems and have been referred to the Occupational Safety and Health Administration. Several notices have prompted evaluation under the hazard assessment process described earlier.

EPA's experience to date suggests certain problems. Of the major chemical companies that employ over 90 percent of the workers and conduct a substantial proportion of research on health and environmental effects, very few have submitted notices of substantial risks. The notices have generally lacked sufficient detail. In almost every case, EPA must contact the submitter for clarification or further information.

EPA is considering clarifying or revising the March policy statement, possibly giving examples of information that should be reported in contrast with examples of inappropriate notices. The revised statement would emphasize that people who submit notices should be prepared to furnish the necessary support data initially or upon request.

Confidentiality. There is an inherent tension in TSCA between requirements to make information available to the public and requirements to protect information entitled to confidential treatment. This conflict emerged first in the context of the inventory reporting regulations. Section 8(b) requires EPA to publish a list of each chemical substance manufactured or processed in the United States. The purpose of the list was twofold: To define "new chemical substances" for purposes of premanufacture notification under section 5(a) and to inform the public of the substances to which they may be exposed. Section 14, however, prohibits disclosure of any confidential business information exempt from disclosure under the Freedom of Information Act (5 U.S.C. 552(b)(4)) except in specific circumstances. According to this provision, EPA could not publish in the inventory a chemical name that would reveal the specific chemical identity of a substance if that identity was entitled to confidential treatment.

Congress intended EPA to preserve confidentiality to the maximum extent practicable without impairing administration of TSCA. Under the inventory reporting regulations, EPA allowed manufacturers, importers, and processors to claim as confidential specific chemical identities. Instead of publishing an incomplete inventory, however, EPA will publish generic chemical names to reveal at least the types of confidential substances in commerce. In complying with the inventory reporting requirements, anyone claiming confidentiality for a chemical identity had to answer detailed questions on the adverse competitive effects of disclosure, the precautions taken to prevent disclosure, and other items. EPA will review these claims critically and will challenge any proposal for a generic chemical name that seems inappropriate.

These same issues will arise for premanufacture notifications submitted to the Agency. EPA is required to publish in the FEDERAL REGISTER notice of receipt of premanufacture notifications. EPA will protect the confidential identities of substances in these notices. In addition EPA will continue to add chemical substances to the inventory once they are manufactured for commercial purposes using the same approach adopted for compiling the initial inventory.

Section 14(b) explicitly provides for disclosure of health and safety studies, but allows for protection of confidential data whose release would disclose the processes used in manufacturing or processing the substance or portions of a mixture. In the premanufacture rulemaking, EPA will solicit comments on its proposed manner for handling specific chemical identities as part of health and safety studies under section 14(b).

Under the inventory reporting regulations, manufacturers were allowed to claim confidentiality for data such as the company name, site, and production quantities. These claims had to be substantiated at the time the information was submitted, but the requirements were less rigorous than for claims with respect to chemical identities. If the claims relating to company name, site, and production data are so numerous as to impair use of the data, EPA may require further substantiation for such claims.

To disclose as much useful information as possible to the public, EPA is developing procedures to aggregate or otherwise mask confidential production, plantsite, and other data. Even when specific production volumes are confidential, the aggregate production for a substance may not be. In devising formulas for masking confidential

information, EPA is consulting the Bureau of the Census and the International Trade Commission which have procedures for this purpose.

EPA has recently adopted final internal security procedures for physical handling of confidential data. The Toxic Substances Control Act Confidential Business Information Security Manual describes the procedures for transmission, receipt, storage, access, removal, and disposal of confidential information submitted to EPA, and the circumstances under which information may be disclosed to EPA's regional offices, laboratories, and other Federal agencies.

In addition, EPA amended its business confidentiality regulations (43 FR 39997, September 8, 1978). Among other things, these amendments bring these regulations in conformity with the procedures required by TSCA's section 14 for handling confidential business information. For example, EPA will notify affected businesses before disclosing confidential business information to the general public and when relevant in proceedings under various EPA statutes. In addition, EPA will notify affected businesses before disclosure to contractors, other Federal agencies, and congressional committees even though such advance notice is not legally required.

PREMANUFACTURE NOTIFICATION

Development of premanufacture notification requirements and implementation of the premanufacture review program is EPA's top priority TSCA activity for fiscal years 1978 and 1979. As provided in section 5, any person intending to manufacture or import a "new" chemical substance must submit a premanufacture notice at least 90 days before he intends to manufacture or import the substance for commercial purposes. Any chemical substance not included on the inventory of substances compiled under section 8(b) will be considered "new". EPA will publish the inventory in early 1979; the premanufacture notification requirements will be effective 30 days later.

EPA will soon propose rulemaking in the FEDERAL REGISTER for reporting "new" chemical substances under section 5. The premanufacture rules will govern notification procedures. Notice forms, an important part of the proposal, will also be published for comment. Testing protocols will not be part of the initial premanufacture proposal. Instead EPA will solicit comment on alternative approaches to testing guidance.

In developing its approach to implementing premanufacture notification, EPA must consider the enormous diversity among chemical substances, manufacturing and processing practices, and chemical uses. For all substances, certain basic information will be required concerning chemical identity, projected uses and exposure, byproducts, disposal methods, and a summary of the toxicity and other tests performed. EPA's evaluation of new substances will depend upon an assessment of their potential health and environmental effects and the potential exposure associated with the manufacture, processing, use, and disposal of the substance.

A manufacturer will also have an opportunity to explain why in his judgment there will be no unreasonable risk, taking into account economic, environmental, and health benefits associated with the substance as well as the nature of the substances for which it may be substituted. EPA will evaluate the notice on the basis not only of the information and justifications provided by the manufacturer, but also in light of available information on similar substances, exposures associated with comparable uses or control technologies, and other relevant factors.

An important aspect of this approach is to insure that the future manufacture and use of the substance do not result in unreasonable risks. For certain substances, EPA may require reporting of any use that would exceed certain conditions of exposure as a "significant new use" under section 5, as discussed below. EPA may frequently use section 6 to require that manufacturers notify employees and customers of the hazards presented by the substances and necessary precautions. A wide variety of other possible actions include adoption of workplace standards by the Occupational Safety and Health Administration.

Over the past several months, EPA has undertaken an intensive effort to develop guidelines for testing new chemical substances. The objective was to identify a relatively inexpensive test system that EPA would consider adequate for developing data on the physical and chemical properties, environmental fate characteristics, and health and ecological effects of new substances. While EPA will continue work on developing a testing program for new substances, the initial premanufacture package will not propose specific testing guidance. Instead, EPA will discuss a possible approach and alternatives and solicit public comment.

Development of testing guidance poses many difficult scientific, economic, and policy issues. Not all tests are appropriate for every chemical substance. The relevance of various tests will depend upon the structure, physical and chemical properties, results of acute and other preliminary tests, and the levels and types of exposure that may be associated with the substance. In addition to complex scientific issues, EpA must consider the impact on innovation. Few manufacturers are willing to invest in extensive testing of a substance if not justified by its potential commercial returns. At the same time, EPA must have adequate data to carry out its responsibilities under TSCA to assess the risks of substances submitted for premanufacture review. These and other issues will be discussed further in the proposed rules for premanufacture notification.

SIGNIFICANT NEW USE

Under section 5, EPA can designate certain uses of chemical substances as "significant new uses" and require notification before a substance is manufactured or processed for that use. This provision recognizes that the risk a substance presents is in large measure determined by its potential exposure. A highly toxic substance that is totally consumed in a closed reaction process can pose relatively little risk of injury. If it is produced in millions of pounds for use in a household product, however, the risks may be substantial.

By designating certain uses of a substance as "significant new uses", EPA will be able to review changes in exposure and prohibit those that may result in unacceptable risks. This is particularly important for following up new chemical substances after premanufacture review. If EPA reviews new substances on the basis of certain conditions of exposure, it may be very important to insure that the substance is not afterwards manufactured or processed for uses that would result in different exposures.

EPA is considering alternative definitions of "significant new uses." Some definitions may focus on particular substances or classes of substances and future uses that could result in potentially hazardous levels of exposure. Others may focus on "uses" broadly defined to include production volumes, distribution, disposal practices, and other factors. Application of any substance or broad categories of substances for designated "uses" would be considered "a significant new use."

EPA is investigating significant new use rules ranging from some very specific to quite general. General ones would apply to "substances (with generally similar toxic properties) for all uses which may result in (some mode of exposure) at (some levels related to the general toxicity) to (some population)". Decisions on significant new use rules must be made while keeping in mind the resources available to review the notices, the feasiblity and effectivness of alternative actions, competing priorities, and the importance of such rules in the overall strategy for reviewing chemical substances.

REGULATORY ACTIONS UNDER SECTION 6

TSCA provides unique authority to reach the critical aspects of most chemical problems. Other laws and regulatory authorities focus on chemical substances as they come out of an outfall pipe or stack, or as they are present in the workplace or in a consumer product. Congress anticipated that EPA under TSCA would take a preventive approach and control hazards at their origins. TSCA's authority extends to every facet of the chemical industry from research and product development, test marketing, manufacturing, processing, distribution, use, to disposal.

Armed with TSCA, EPA can address hazards that escape the reach of other laws. Sometimes regulations under media-specific laws have resulted in simply transferring problem chemicals from one medium, which is regulated, to another that is not (or not yet). Under TSCA, EPA can act to control the total risk from substance, in any medium or content.

EPA will initially emphasize control of known hazards posed by existing substances plus hazards identified in the premanufacture notification process for "new" substances. EPA's first action under TSCA was to promulgate regulations on the labeling and disposal of polychlorinated biphenyls (PCBs). The second phase of PCB regulations, implementing a ban on manufacture, processing, distribution, and use was formally proposed on June 7, 1978.

Last March, in a joint action with the Food and Drug Administration and the Consumer Product Safety Commission, EPA banned most aerosol uses of chlorofluorocarbons (CFC's). EPA is now investigating ways to further reduce CFC emissions, specifically from such nnonaerosol sources as air conditioners, refrigerators, solvents, and foam-blowing.

A number of well-recognized hazardous substances and alternative approaches to them are being evaluated. Among the substances are asbestos, cadmium, benzidine dyes, mercury, lead, arsenic, and trichloroethylene.

Considering the breadth of TSCA's mandate, a most significant activity is the development of a systematic approach for selecting substances for possible regulatory action. An earlier section described in some detail the hazard assessment process developed for this purpose. As EPA gains more knowledge about the effects and exposure of substances, this process will be refined.

EPA intends to make wide and varied use of categories under different sections of the Act. Section 26(c) provides that any authority under TSCA that applies to a chemical substance or mixture may also be applied to a category of chemical substances or mixtures. EPA may define categories in any reasonable way, except that substances cannot be treated categorically solely on the basis that they are "new".

EPA is considering the use of categories in developing a labeling requirement. At present few chemical substances are labeled with warnings to workers, consumers, and others on their chronic effects. EPA is now investigating Federal labeling requirements and existing practices in industry. Ideally, EPA could create under the auspices of TSCA a uniform system for labeling chemical hazards wherever they appear—in research laboratories, manufacturing sites, consumer products or wherever. The foundation of any labeling system is the classification of various levels of acute and chronic hazards. The categories evolving from this effort could affect many aspects of TSCA implementation, such as reporting requirements or priorities for hazard assessment.

EPA economists will carefully analyze the potential impacts of any action under TSCA. Because many chemical firms have very few employees, regulatory actions under TSCA will frequently affect small businesses. EPA and the Small Business Administration have discussed loans to help small manufacturers and processors bear the costs associated with TSCA requirements.

Ideally, the influence of TSCA implementation will go far beyond specific regulatory actions. Actions to prompt voluntary measures by industry will be a key element of EPA's strategy. Labeling requirements, for example, may significantly affect industry behavior. Public disclosure of the relative hazards of chemical products might also create a market demand for safer products.

Similarly, EPA hopes to raise awareness among chemical manufacturers, insurance companies, investors, and others that evaluating new products for their risks to human health and the environment is highly important. Using technology to reduce risks from chemical substances is a major feature of many environmental laws, including TSCA. EPA will work with the chemical industry to encourage technological solutions whenever appropriate, instead of imposing more costly restrictions under TSCA.

INTEGRATED APPROACH TO TOXIC SUBSTANCES

An integrated approach to toxic substances is a major Agency-wide objective. TSCA gives EPA this opportunity. It extends to all aspects of a substance's lifecycle and enables EPA to use its other authorities more effectively.

For example, data developed under the testing provisions of TSCA on the risks of pollutants in drinking water or in ambient air could provide the basis for actions under the Safe Drinking Water Act or Clean Air Act. Information on the effluent and emissions associated with the manufacture of new substances will come from premanufacture notification. If necessary, EPA could impose effluent limitations on a plant under the Clean Water Act to control discharge of toxic substances. Information on chemical wastes and disposal methods may prompt action under the Resource Conservation and Recovery Act.

As an element of a strategy for integrating control over toxic substances, EPA has established the Toxic Substances Priorities Committee. it is chaired by the Assistant Administrator for the Office of Toxic Substances and consists of high level representatives from all the other Assistant Administrators and the Office of General Counsel. Consistency in EPA's various actions to protect against the risks from substances in different media is a main concern of the Committee. TSCA, the Resource Conservation and Recovery Act, and amendments to the Clean Air and Clean Water Acts, are the source of many new EPA programs to deal with toxic substances. The Committee will guide appropriate regulatory actions under all these laws at an early stage. It will also serve to coordinate information collection and contractor efforts, and will identify gaps or duplication.

The EPA Regional Offices will play an essential role in linking existing programs under the Clean Air Act, Clean Water Act, other media-specific authorities with TSCA. The key to controlling toxic substances is integration, not the establishment of one more new "categorical" program under TSCA.

EPA envisions an ideal regional toxic substances program to include a broad range of activities: developing communication channels among EPA's single media programs; working with State agencies and other Federal regional programs; coordinating information exchange, monitoring and enforcement; creating procedures for systematic evaluation and response to chemical crises; assisting industry in complying with TSCA requirements; developing programs for greater public understanding of toxic substances problems; and identifying and analyzing regional toxic substances problems.

INTERNATIONAL APPROACHES TO TOXIC SUBSTANCES

Every aspect of TSCA has international ramifications. Actions affecting

manufacturers also apply to importers and thereby affect foreign chemical producers. Foreign governments and manufacturers have expressed particular interest in the approach EPA is taking toward "new" chemical substances. EPA has met with representatives of governments of the European Communities, Canada, and Japan, and others to discuss these requirements especially in relation to the other governments' approaches to "new" substances. The risks from many substances such as polychlorinated biphenyls and chlorofluorocarbons cannot be dealt with effectively by any one nation alone.

Several governments have recently enacted laws dealing with toxic substances and many others are considering legislation. Because most nations are in a formative stage of implementing their authorities, there is now a unique opportunity to develop consistent approaches and to avoid creation of unnecessary barriers to international trade. In April 1978, EPA participated in discussions at Stockholm, Sweden, with representatives of 16 nations and several international organizations concerned with toxic substances. The Stockholm delegates identified several priority areas for international initiative.

Many of the Stockholm concerns are addressed in the ambitious program of the Organization for Economic and Cooperative Development (OECD). These efforts include the development of consistent testing methods and standards for good laboratory practices and effective means of enforcing them. Also underway is an information exchange system for technical data and notices of administrative actions. Other experts are examining the legal and policy impediments to disclosure of health and safety data and methods for analyzing the economic impacts of regulatory actions. The United States is committed to such international harmonization efforts.

Appendix—Organization of the Office of Toxic Substances

The chart below indicates the organization for the Office of Toxic Substances (OTS). The Assistant Administrator (AA) for Toxic Substances reports directly to the EPA Administrator. Under the AA, are four Deputy Assistant Administrators (DAA's). The DAA for pesticide programs is primarily responsible for implementing the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The other three DAA's are responsible for implementing the Toxic Substances Control Act (TSCA). Over the next few years, OTS will integrate many of the scientific, technical, and other support activities common to implementation of FIFRA and TSCA.

The following briefly describes the general functions of each of the three Deputy Assistant Administrators responsible for implementation of TSCA.

CHEMICAL CONTROL

The Deputy Assistant Administrator for Chemical Control is responsible for the regulatory control program under sections 5 and 6 of TSCA. The Control Action Division determines whether risks posed by chemical substances to health or the environment are "unreasonable" and takes regulatory actions under section 6. The Premanufacture Review Division is responsible for reviewing new substances and significant new uses under section 5.

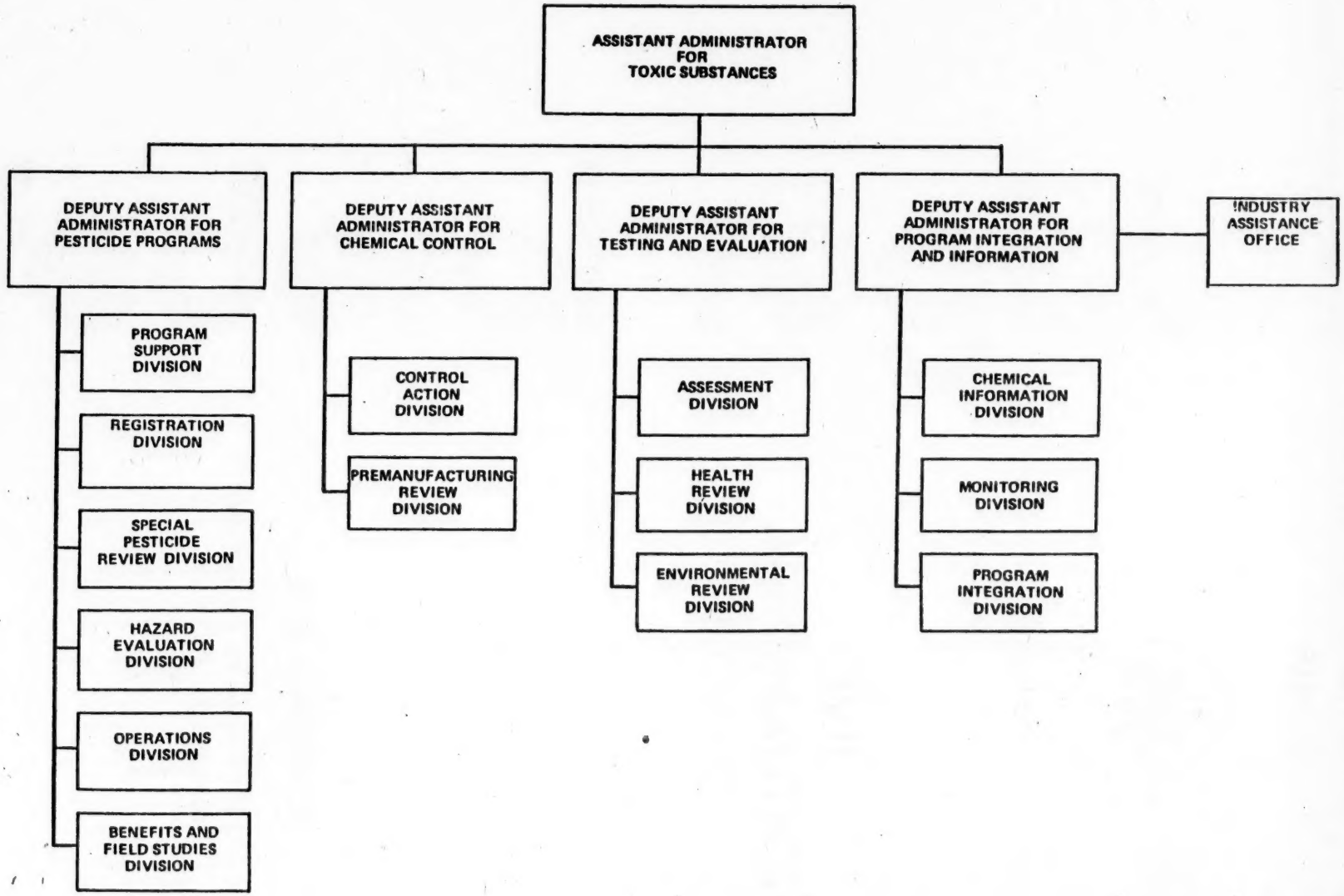
TESTING AND EVALUATION

The Deputy Assistant Administrator for Testing and Evaluation is responsible for identifying and evaluating hazards that chemical substances and mixtures may present to health and the environment. The Assessment Division is primarily responsible for the Hazard Assessment Process and for selecting substances to be tested under section 4. The Health Review Division develops testing standards for health effects and assesses risks to health. The Environmental Review Division develops testing standards for evaluating chemical fate, persistence, and environmental effects, and assesses environmental risks.

PROGRAM INTEGRATION AND INFORMATION

The Deputy Assistant Administrator for Program Integration and Information is responsible for promoting integration and coordination of toxic substances activities, and for information development and retrieval. The Industry Assistance Office is a focal point for communication with the industrial community concerning implementation of TSCA. The Chemical Information Division is responsible for implementing the reporting and recordkeeping rules and regulations under section 8 and for developing procedures for automated storage, retrieval, and processing of information. The Monitoring Division is responsible for environmental, human, animal, and biota monitoring and mass balance studies in support of OTS activities. The Program Integration Division is responsible for coordination of TSCA activities with other EPA programs, regional offices, Federal, State, and local agencies, and with foreign governments and organizations.

OFFICE OF TOXIC SUBSTANCES



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